National Environmental Laboratory **Accreditation** Conference

nelac

ACCREDITATION PROCESS

Proposed Changes

May 1, 1998

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ACCREDITATION PROCESS

N O T E: ***The additions and ~~deletions~~ to the approved standards being submitted by the Accreditation Process Committee for vote are marked as in this note.***

4.0 ACCREDITATION PROCESS

(NB. MANY OF THE STANDARDS AND ELEMENTS LISTED IN THIS CHAPTER ARE REFLECTIVE OF STANDARDS SET FORTH IN CHAPTERS DEALING WITH DETAILED EXPLANATIONS OF THESE ELEMENTS. THEREFORE, IT IS ANTICIPATED THAT SOME OF THE DETAILS MAY CHANGE AS THE DISCUSSIONS AND CONCLUSIONS IN THESE CHAPTERS CHANGE.)

4.1 COMPONENTS OF ACCREDITATION

The components of accreditation include review of personnel qualifications, on-site assessment proficiency testing and quality assurance/quality control standards. These criteria must be fulfilled for accreditation. The components and criteria are herein described. Details of some of the requirements described below will be found in other sections of these Standards.

4.1.1 Personnel Qualifications

~~A~~ Persons who do~~es~~ not meet the education credential requirements of 4.1.1.1 of the NELAC compliant standards and ~~is~~ are the technical director(s) ~~responsible party or assistant responsible party~~ on the date that the laboratory becomes subject to these regulations, shall ~~may~~ qualify as technical director(s) ~~director/assistant director~~ of that laboratory if that laboratory can demonstrate the ability to comply with the Accrediting Authority's proficiency testing and quality control requirements and possesses the requisites experience.

4.1.1.1. Definition, Technical Director(s) ~~responsible party of record~~

The technical director(s) ~~responsible party of record~~ means a full-time member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory procedures and reporting of results. The title of such person may include but is not limited to laboratory director, technical director, laboratory supervisor or laboratory manager. His/her name must appear in the national database. This person's duties shall include, but not be limited to, monitoring standards of performance in quality control and quality assurance; monitoring the validity of the analyses performed and data generated in the laboratory to assure

reliable data; ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and providing educational direction to laboratory staff. An individual shall ~~may~~ not be the technical director(s) ~~responsible party of record~~ of more than one accredited ~~approved~~ environmental laboratory without authorization from the primary Accrediting Authority. Circumstances to be considered in the decision to grant such authorization shall ~~may~~ include, but not be limited to, the extent to which operating hours of the laboratories to be directed overlap, adequacy of supervision in each laboratory, and the availability of environmental laboratory services in the area served. The technical director(s) ~~A responsible party of record~~ who is absent for a period of time exceeding 10 consecutive working ~~business~~ days shall designate another full-time staff member meeting the qualifications of the technical director(s) ~~responsible party of record~~ to temporarily perform this function. If this absence exceeds 45 consecutive working ~~business~~ days, the primary accrediting authority shall be notified in writing.

Qualifications of the technical director(s) ~~responsible party of record~~.

a) The technical director(s) ~~responsible party of record~~ of an accredited ~~approved~~ environmental laboratory engaged in chemical analysis shall be a person with a bachelors degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least 24 college semester credit hours in chemistry and at least two years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory is seeking approval. A masters or doctoral degree in one of the above deciplines may be substituted for one year of experience.

b) The technical director(s) ~~responsible party of record~~ of an accredited ~~approved~~ environmental laboratory ~~engaged in, but~~ limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical or environmental sciences, or two years of equivalent and successful college education, with a minimum of 16 college semester credit hours in chemistry. In addition, such a person shall have at least two years of experience performing such analysis.

c) The technical director(s) ~~responsible party of record~~ of an accredited ~~approved~~ environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelors degree in microbiology, biology, ~~or~~ environmental sciences, physical sciences or engineering with a minimum of 16 college semester credit hours in general microbiology and biology and at least two years of experience in the environmental analysis of representative analytes for which the laboratory is seeking approval. A masters or doctoral degree in one of the above deciplines may be substituted for one year of experience.

A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four college semester credit hours in general microbiology may be the technical director(s) ~~responsible party of record~~ of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform and standard plate count. Two years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one year of experience in environmental analysis.

d) The technical director(s) ~~responsible party of record~~ of an accredited ~~approved~~ environmental laboratory engaged in radiological analysis shall be a person with a bachelor’s degree in chemistry, ~~or~~ physics or engineering with 24 hours of chemistry with two or more years of experience, one of these in a supervisory capacity, in the radiological analysis of environmental samples. A masters or doctoral degree in one of the above deciplines may be substituted for one year experience.

The technical director(s) ~~responsible party of record~~ of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements:

i) For procedures requiring the use of a transmission electron microscope, a bachelor's degree, successful completion of ~~specialized~~ courses in the use of the instrument, and one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

ii) For procedures requiring the use of a polarized light microscope, an associate's degree or two years of college study, successful completion of formal coursework in polarized light microscopy, and one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

iii) For procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers, an associate's degree or two years of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one year of experience, under supervision, in the use of the instrument.

f) The technical director(s) ~~responsible party of record~~ of an accredited ~~approved~~ environmental laboratory engaged in the examination of radon in air shall have at least an associate’s degree or two years of college and one year of experience in radiation measurements, including at least one year of experience in the measurement of radon and/or radon progeny.

4.1.1.2 Personnel Qualification Clarifications and Exceptions

~~a) For laboratories engaged in more than one environmental analysis (e.g. microbiology, organic chemistry, inorganic chemistry and radiological analysis), one or more persons hereafter known as assistant responsible parties may complement the director, provided that each has an academic degree and the required appropriate credit hours and years of experience as prescribed in this section. The title of an assistant responsible party can include, but not be limited to, assistant director, assistant manager, technical expert of senior analyst. Each shall be responsible for only the areas of environmental analysis for which he or she meets the qualifications required by this section.~~

a)~~b~~) Notwithstanding any other provision of this section, a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements serving as the director of the accredited ~~approved~~ laboratory

devoted exclusively to the examination of environmental samples taken within such facility. Such accreditation ~~approval~~ for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit.

b)~~c~~) A full-time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision in environmental analysis shall be deemed to meet the requirements for serving as the director of an accredited ~~approved~~ laboratory devoted exclusively to the examination of environmental samples taken within such facility for the scope of that facility's regulatory permit.

4.1.2 On-Site Assessments

On-Site assessments are a requirement of the Accreditation Process and a summary of the process requirements are described. Refer to On-Site Assessment (Chapter 3) for additional information regarding frequency, procedures, criteria, scheduling and documentation of on-site assessments. On-Site assessments shall ~~may~~ be of two types: announced and unannounced. The on-site assessment of each accredited laboratory ~~facility~~ must be performed a minimum of one time per two years. On-site assessments may be conducted more frequently for cause or at the option of the primary accrediting authority. Situations which might trigger more frequent on-site assessments include, review of a previously deficient on-site assessment, poor performance on a PT sample, change in other accreditation elements, or other information concerning the capabilities or practices of the accredited laboratory. The on-site assessment ensures that the environmental laboratory is in compliance with NELAC standards. ~~capable of performing analyses to the level, precision and accuracy required by the specific method or performance based method~~.

The responsibility and accountability for meeting the NELAC standards are the responsibility of the primary accrediting authority. The primary accrediting authority has the responsibility for conducting on-site assessments for national accreditation based on the following factors:

a) Individual sites are subject to the same application process, ~~fees,~~ assessments and other requirements as environmental laboratories. Any remote laboratory sites are considered separate sites and subject to

separate on-site assessments, again provided that the analysis or any portion of the analysis take place at that site. This includes mobile laboratories which are on the same site for a period exceeding 90 continuous days per year ~~3 months~~. A mobile laboratory owned by an accredited fixed based laboratory which is equipped with instrumentation to address a temporary situation, not to exceed 3 months, and is performing a subset of analyses for which the parent laboratory is accredited, is considered an extension of the parent laboratory and will not require separate accreditation ~~certification~~. A location that only does sample collections is not considered an environmental laboratory and shall ~~will~~ not be subject to these requirements;

b) The assessment may consist of all of the fields of testing and/or methods for which the laboratory wants to obtain accreditation;

c) The laboratory may be required to analyze PT samples during the on-site assessment under the observation of an assessor;

d) The number of assessors conducting the on-site assessment should be appropriate for the laboratory's scope and testing. ~~and the accrediting authority should be sensitive to fee structure, cost, and the number of assessors;~~

e) The on-site assessment should be conducted during normal working hours.

Laboratories shall ~~will~~ be furnished with a report documenting any deficiencies found by the assessor. This shall ~~will~~ be known as a Deficiency Report. ~~It should be noted, the assessor is not limited to these factors in reaching an evaluation and conclusion~~. ~~Other factors may be considered and must be documented as appropriate~~. All such reports are public record and any or all of the information contained therein may be put into the National Database.

4.1.3 Corrective Action Reports In Response to On-Site Assessment

A ~~C~~corrective ~~A~~action ~~R~~report must be submitted by the laboratory to the primary accrediting authority in response to any ~~D~~deficiency ~~R~~report received by the laboratory ~~facility~~ after an on-site assessment. The corrective action report shall ~~will~~ include the action

that the laboratory shall ~~will~~ implement to correct each deficiency and the time period required to accomplish the corrective action.

a) The primary accrediting authority ~~or authorized third party~~ shall ~~must~~ present a ~~D~~deficiency ~~R~~report to the laboratory within 21 ~~30~~ working days of the on-site assessment.

b) After being notified of deficiencies, the laboratory shall ~~will~~ have 21 ~~30~~ working days from the date of receipt of the deficiency report to provide a ~~C~~corrective ~~A~~action ~~R~~report. ~~to correct deficiencies noted in the Deficiency Report.~~

c) The primary accrediting authority shall ~~will~~ respond to the action noted in the ~~C~~corrective ~~A~~action ~~R~~report within 21 ~~30~~ working days of receipt ~~receiving it~~.

d) If the corrective action report (or a portion) is deemed unacceptable to remediate a deficiency the laboratory shall ~~will~~ have an additional 21 ~~30~~ working days to submit a revised corrective action report.

e) If the corrective action report is not acceptable to the primary accrediting authority after the second submittal, the laboratory shall ~~can~~ have accreditation revoked pursuant to Section ~~4.4.2~~ ~~and~~ 4.4.3 for all or any portion of its scope of accreditation for any or all of a field of testing, ~~category or~~ a method, or analyte within a field of testing. ~~category~~.

f) All information included and documented in a ~~D~~deficiency ~~R~~report and the ~~C~~corrective ~~A~~action ~~R~~report are considered to be public information and are to be released pursuant to Chapter 3, section 3.7.5. Other accrediting authorities ~~states~~ participating in the NELAP would have access to this information through a national database.

g) If the laboratory fails to implement the corrective actions as stated in their corrective action report, ~~to correct deficiencies noted within the required time period,~~ accreditation for fields of testing, ~~categories or~~ specific methods, or analytes within those fields of testing shall ~~categories will~~ be revoked. All such deficiency and corrective action reports are public record and any or all of the information contained therein may be put into the

~~N~~national ~~D~~database. Proprietary data and Confidential Business Information will be excluded ~~excepted~~ from all public records.

4.1.4 Proficiency Testing Samples

~~When appropriate for the evaluation and available,~~ A~~a~~ critical component of laboratory assessments is the analysis of proficiency testing (PT) samples. Refer to Proficiency Testing (Chapter 2) for additional information. PT samples are used and evaluated in the accreditation process as follows:

a) Each laboratory seeking accreditation must receive, and analyze initial PT samples from a NELAP approved PT study provider for each field of testing (program-method-analyte) in which they are requesting accreditation.

b) Unless otherwise specified by the proficiency testing standard, ~~E~~each laboratory seeking or maintaining accreditation shall be required to perform analyses on one PT sample twice per year in each field of testing (program-method-analyte) for which they have applied for accreditation or for which they are currently accredited.

c) The laboratory shall ~~will~~ be informed of their score on the PT samples by the primary accrediting authority or the NELAP approved PT provider within 15 working ~~21~~ days from the closing date of submission. The results of all of the PT sample tests including “pass” or “fail” shall ~~will~~ be part of the public record. The result of passing or failing a PT sample shall ~~will~~ apply to all accredited methods a laboratory employs for an analyte.

d) When a laboratory initially requests accreditation, it must successfully analyze two sets of PT samples, the analyses to be performed 21 ~~30~~ working days apart. Each set shall ~~will~~ contain one sample for each requested field of testing (program-method-analyte). Once a laboratory has been granted accreditation status, it must maintain a history of at least two passing results out of the most recent three for each field of testing (program-method-analyte).

e) The results of the PT sample analyses shall ~~will~~ be considered by the primary accrediting authority, ~~along with other information obtained from announced~~

~~and unannounced assessments~~ in determining whether accreditation should be granted, denied, revoked, or suspended pursuant to this Chapter, for a field of testing (program-method-analyte) or an analyte within a field of testing (program-method-analyte).

4.1.5 Accountability for Analytical Standards

Elements in NELAP ~~a national program~~ that shall ensure consistency and promote the use of quality assurance/quality control procedures to generate quality data for regulatory purposes are:

a) NELAC requires that each laboratory seeking NELAP ~~national~~ accreditation have a named ~~Q~~quality ~~A~~assurance ~~O~~officer or a person designated as accountable for data quality. The ~~Q~~quality ~~A~~assurance ~~O~~officer shall ~~will~~ be a person other than any supervisor of laboratory analysts, who reports directly to the laboratory management and not to the laboratory supervisor in matters related to quality assurance and quality control of analyses, methods relating to these analyses, and instrumentation.

b) NELAC requires that each laboratory seeking NELAP ~~national~~ accreditation have a developed and maintained Quality Assurance Manual on-site, as required in Chapter 5. The primary accrediting authority ~~or assessor body~~ may request the manual prior to the on-site assessment.

c) The primary accrediting authority shall ~~will~~ consider that the accountability for negligence, the falsification of data, ~~records or instrument parameters~~ shall ~~will~~ rest upon the analyst, the laboratory management and the company.

4.1.6 Fee Process for National Accreditation

Refer to Policy and Structure, Chapter 1, specifically funding of this program (Section 1.6.2.3.3 ~~1.10~~)

~~The cost incurred in the application process for national environmental laboratory accreditation will be called an accreditation fee.~~

~~Where required and if applicable, accreditation fees will be paid in accordance with existing state regulations, levels and practices to the accrediting authority granting the accreditation.~~

Where required and if applicable, the level and timing of fee payments shall ~~will~~ be established by the primary accrediting authority to which the laboratory is applying for accreditation. Additional fees on the laboratory may be levied by other secondary accrediting authorities with which the laboratory chooses to do business.

4.1.7 Application

The NELAP ~~National Environmental Laboratory Accreditation Program~~ encompasses a standardized set of elements in each application for accreditation that shall ~~will~~ be reported to and recorded in the national database. The application package includes any specific state regulatory requirements that are essential for accreditation within an individual state.

An accrediting authority participating in NELAC shall ~~will~~ include in its application form the following:

a) Legal name of laboratory
b) Laboratory mailing address
c) Billing address (if different from b)
d) Name of owner
e) Address of owner
f) Location (full address) of laboratory
g) Name and phone number of technical director(s),however named, and the lead technical director (if applicable) ~~responsible person of record~~
h) Name and phone number of Quality Assurance Officer
i) Name and phone number of laboratory contact person
j) Laboratory hours of operation
k) Primary Accrediting Authority
l) Fields of Testing ~~Categories~~ for which the laboratory is requesting accreditation
m) Methods employed including analytes
n) Description of laboratory type (for example)
   - Commercial
   - Federal
   - Hospital or health care
   - State
   - Academic Institutes
   - Public water system
   - Public wastewater system
   - Industrial (an industry with discharge permits)
   - Mobile
   - Other (Describe)_____
o) Certification of compliance by laboratory management (*vide infra*: 4.1.9)
p) ~~Applicable~~ ~~f~~Fee enclosed (if applicable)

q) Description of geographical location
r) FAX number
s) Lab identification number (for renewal)
t) Quality ~~Assurance~~ Manual

A laboratory seeking renewal of accreditation shall ~~will~~ follow the process outlined by the accrediting authority in which they are currently accredited.

4.1.8 Change of Ownership and/or Location of Laboratory

Accreditation may be transferred when the legal status or ownership of an accredited laboratory changes without affecting its staff, equipment, and organization. The primary accrediting authority may charge a transfer fee and may conduct an On-site assessment to verify affects of such changes on laboratory performance.

The following conditions apply to the change in ownership and/or the change in location of a laboratory that has national accreditation.

a) Any change in ownership and/or location of an accredited laboratory must be reported in writing to the primary accrediting authority and entered into the national database by the primary accrediting authority.

b) Such a change in ownership and/or location shall ~~will~~ not necessarily require reaccreditation or reapplication in any or all of the categories in which the laboratory is currently accredited.

c) Change in ownership and/or location may require an ~~O~~on-site assessment with the elements of the assessment being determined by the assessor ~~inspector~~.

d) Any change in ownership must assure historical traceability of the laboratory accreditation number(s).

e) For a change in ownership, the following conditions must be in effect:

   1~~i~~. The previous (transferring) owner must agree in writing, before the transfer of ownership takes place, to be accountable and liable for any analyses, data and reports generated up to the time of legal transfer of ownership; and

2~~ii~~. The buyer (transferee) must agree in writing to be accountable and liable for any analyses, data and reports generated after the legal transfer of ownership occurs.

3~~iii~~ All records and analyses performed pertaining to accreditation must be kept for a minimum of 5 years and are subject to inspection by the accrediting authorities during this period without prior notification to the laboratory. This stipulation is applicable regardless of change in ownership, accountability or liability.

4~~iv~~. If ownership is transferred, the transferee may not be responsible for payment of fees to the accrediting authorities during the remainder of the yearly period, provided that the previous owner has fully paid the required fees to the accrediting authorities.

4.1.9 "Certification of Compliance" Statement

The following "Certification of Compliance" statement must accompany the application for laboratory accreditation. It must be signed and dated by both the laboratory management and the quality assurance officer, or other designated person, for that laboratory.

CERTIFICATION BY APPLICANT

The applicant understands and acknowledges that the laboratory is required to be continually in compliance with the National Environmental Laboratory Accreditation Conference (NELAC) standards and shall ~~will~~ be subject to the penalty provisions provided therein.

The applicant understands and acknowledges that accreditation is specifically subject to unannounced assessments.

Authorized representatives of any primary accrediting authority may make an announced or unannounced assessment, search, or examination of an accredited or interim accredited ~~approved~~ laboratory whenever the primary accrediting authority, at its discretion, considers such an assessment, search or examination necessary to determine the extent of the laboratory's compliance with the NELAC standards. Additionally, the applicant authorizes the primary accrediting authority assessor ~~inspector~~ to; 1) make copies of any analyses or records relevant to the accreditation process, and 2) remove any or all such copies from the facility for

purposes of assessment or regulatory enforcement. Any refusal to allow entry to the primary accrediting authority's representatives during normal business hours or to allow copies of records relevant to laboratory accreditation to be made shall constitute a violation of a condition of accreditation and grounds for denial, suspension,or revocation of accreditation.

The applicant hereby certifies that all accredited environmental analyses performed are done in accordance with the NELAC_standards.

I hereby certify that I am authorized to sign this application on behalf of the applicant/owner and that there are no misrepresentations in my answer to the questions on this application.

Signature Quality Assurance Officer or other designated ~~responsible~~ individual	Name of Quality Assurance Officer
Print Name of Applicant Laboratory (Legal Name)	Date
Signature Technical Director(s) ~~Responsible Person of Record~~	Name Technical Director(s) ~~Responsible Person of Record~~

4.2 PERIOD OF ACCREDITATION

For a laboratory in good standing, the period for accreditation within fields of testing ~~categories~~ for methods or analytes shall ~~will~~ be 12 months and will be considered to be ongoing once a laboratory has been accredited for that field of testing ~~category~~ ~~or~~ method or analyte within a field of testing ~~category~~. To maintain accreditation the laboratory shall meet the requirements of Section 4.3, Maintaining Accreditation. Failure to meet the requirements delineated in Section 4.3 shall constitute grounds for suspension or revocation of accreditation as specified in Section 4.4. Additionally, failure to pay the required fees as determined by the accrediting authority within the stipulated deadlines or by the stipulated dates shall ~~may~~ result in ~~suspension or~~ revocation of accreditation. This information may be entered into the ~~N~~national ~~D~~database in a timely and effective manner. The NELAP recognizes that different accrediting authorities operate the yearly period with different start times. The individual laboratory being accredited is responsible for tracking an_accrediting authority's period of accreditation and is responsible for paying the necessary

fees (if applicable) to those accrediting authorities to maintain accreditation.

4.3 MAINTAINING ACCREDITATION

Accreditation remains in effect until revoked by the accrediting authority, withdrawn at the written request of the accredited laboratory, or until expiration of accreditation period. To maintain accreditation, the accredited laboratory shall complete or comply with elements 4.3.1 TO 4.3.3. Failure to complete or comply with these elements shall ~~may~~ be cause for suspending or revoking accreditation as specified in section 4.4 of this chapter.

4.3.1 Quality Systems

Laboratories seeking accreditation under NELAP must assure consistency and promote the use of quality assurance/quality control procedures. Chapter 5, Quality Systems provides the details concerning quality assurance and quality control requirements for the evaluation of laboratories. The quality assurance policies, which establish essential quality control procedures, are applicable to all environmental laboratories regardless of size, volume of business and fields of testing. Failure to maintain, revise, or replace any of these key components may be cause for suspending or revoking a laboratory's accreditation status, as specified in section 4.4 of this chapter.

~~The following applicable requirements are provided in Chapter 5 (Quality Systems) and associated Appendix: Organization and Management; Quality System - Establishment, Audits, Essential Quality Controls and Data Verification; Personnel; Physical Facilities - Accommodation and Environment; Equipment and Reference Materials; Measurement Traceability and Calibration; Test Methods and Standard Operating Procedures; Sample Handling, Sample Acceptance Policy and Sample Receipt; Records; Laboratory Report Format and Contents; Subcontracting Analytical Samples; Outside Support Services and Supplies; and Complaints. Appendix D - Essential Quality Control Requirements for Chemical testing; Whole Effluent Toxicity; Microbiology; Radioanalysis; and Air Testing.~~

4.3.2 Notification and Reporting Requirements

The accredited laboratory shall notify the accrediting authority of any changes in key accreditation criteria within 30 working ~~calendar~~ days of the change. This written notification change includes~~ing~~ but is not ~~necessarily~~ limited to the laboratory ownership,

location, key personnel, and major instrumentation. ~~The accredited laboratory shall also comply with any other reporting requirements identified in these guidelines~~. All such updates are public record and any or all of the information contained therein may be put into the national database.

4.3.3 Record Keeping and Retention

All laboratory records associated with accreditation parameters shall meet the requirements of Chapter 5, Section 5.12 and ~~must be easily accessible, including raw and processed data associated with each analysis, changes in method standard operating procedures, or the laboratory quality assurance plan,~~ shall be maintained for a minimum of five years unless otherwise designated for a longer period in another regulation or authority. In the case of data used in litigation, the laboratory is required to store such records for a longer period upon written notification from the accrediting authority.

4.4 DENIAL, SUSPENSION, AND REVOCATION OF ACCREDITATION

4.4.1 Denial

Denial - shall mean to refuse to accredit in total or in part a laboratory applying for initial accreditation or resubmission of initial application.

b) Reasons to deny an initial application ~~may~~ shall include:

1) Failure to submit a completed application.

2) Failure of laboratory staff to meet the personnel qualifications as required by the NELAC standards. These qualifications ~~may~~ shall include education, training and experience requirements.

3) Failure to successfully analyze and report proficiency testing samples as required by the NELAC standards, Chapter 2.

~~4) Failure to attest that analysis are performed by methodologies as required by the NELAC standards Chapter b.~~

~~5~~4) Failure to respond to a ~~D~~deficiency ~~R~~report from the ~~O~~on-~~S~~site assessment with a corrective action report within the ~~specified amount of time.~~ required 21 working days after receipt of the deficiency report.

~~6~~5) Failure to implement the ~~c~~Ccorrective ~~a~~Aactions detailed in the corrective action report within the ~~specified~~ time frame as specified ~~required~~ by the ~~NELAC standards.~~ primary accrediting authority.

~~7~~6) Failure to pay required fees.

~~8~~7) Failure to pass required on-site assessment(s) as specified in the NELAC standards, Chapter 3.

8) Misrepresentation of any fact pertinent to receiving or maintaining accreditation.

9) Denial of entry during normal business hours for an on-site assessment as required by the NELAC standards, Chapter 3.

~~b) A laboratory shall have two opportunities to correct the areas of deficiencies which results in a denial of accreditation.~~

~~c~~b) If the laboratory is not successful in correcting the deficiencies as required by the NELAC standards, the laboratory must wait six months before again reapplying for accreditation.

~~d~~c) Upon reapplication, the laboratory may again be responsible for all or part of the fees as applicable incurred as part of the initial application for accreditation.

~~e~~d) No laboratory's accreditation ~~will~~ shall be denied without the right to due process. ~~as set forth in Section 4.7 of this Chapter.~~

4.4.2 Suspension

Suspension - shall mean the temporary removal of a laboratory's accreditation for a defined period of time which shall not exceed six months. The purpose of suspension is to allow a laboratory time to correct deficiencies or area of non-compliance with the NELAC standards.

a) A laboratory's accreditation ~~may~~ shall be suspended in total or in part. The laboratory shall retain ~~those areas of~~ accreditation for the field of testings, methods and analytes where it continues to meet the requirements of the NELAC standards.

b) Reasons for suspension ~~may~~ shall include:

1) ~~Failure to successfully analyze and report PT samples pursuant to the NELAC standards, Chapter 2;~~ If the primary accrediting authority finds during the on-site assessment that the public interest, safety or welfare imperatively requires emergency action;

2) ~~Failure to submit an acceptable corrective action report, in response to a deficiency report and failure to implement corrective action(s) related to any deficiencies found during laboratory assessments within the required time period as required by the NELAC standards;~~ Failure to complete proficiency testing studies and maintain a history of at least two successful proficiency testing studies for each affected accredited field of testing out of the three most recent proficiency testing studies as defined in NELAC, Chapter 2;

~~2~~3) Failure to notify the primary accrediting authority of any changes in key accreditation criteria, as set forth in Section 4.3.~~4~~2 of this Chapter;

~~3)~~ ~~Failure to perform all accredited tests in accordance with the NELAC standards; and~~

~~4)~~ ~~Failure to meet all the requirements of the NELAC standard, Chapter 5.~~

4) When the only qualified technical director is absent for a period of time exceeding 10 consecutive working days but less than 45 consecutive working days.

5) When a weather related or other natural disaster strikes the area in which the laboratory is located and precludes the operation of the facility for a period exceeding five (5) working days.

~~d~~c) A suspended laboratory cannot continue to analyze samples for the affected fields of testing for which it holds accreditation.

~~1)~~ ~~Can not continue to analyze samples for the affected fields of testing for which it holds accreditation; and~~

~~2)~~ ~~Shall be immediately suspended (without appeal rights) due to unacceptable proficiency testing sample results~~.

~~g~~d) The laboratory's suspended accreditation status will change to accredited when the laboratory demonstrates to the primary accrediting authority that the laboratory complies with the NELAC standards.

~~c~~e) A suspended laboratory would not have to reapply for accreditation if the cause/causes for suspension are corrected within six months.

~~h~~f) If the laboratory fails to correct the causes of suspension within six months after the effective date of the suspension, the primary accrediting authority shall revoke in total or part the laboratory's accreditation.

~~f~~g) No laboratory's accreditation ~~will~~ shall be suspended without the right to due process as set forth ~~in Section 4.7 of this Chapter~~ by the primary accrediting authority.

4.4.3 Revocation

Revocation - shall mean the in part or total withdrawal of a laboratory's accreditation by the accrediting authority.

a) The accrediting authority shall revoke a laboratory's accreditation, in part or in total for failure to correct the deficiencies as set forth in section 4.1.3 e) of this Chapter and failure to correct the reasons for being suspended ~~after being suspended~~. The laboratory shall retain ~~those areas of~~ accreditation for the fields of testing, methods and analytes where it continues to meet the requirements of the NELAC standards.

b) Reasons for revocation in part or in total include a laboratory's:

   1) Failure to submit an acceptable corrective action report, in response to a deficiency report and failure to implement corrective action(s)related to any deficiencies found during a laboratory assessment. The laboratory may submit two corrective action reports within the time limits specified in section 4.1.3.

   2) ~~Failure to successfully analyze and report PT samples pursuant to the NELAC standards, Chapter 2.~~ After being suspended due to failure of proficiency testing samples, if the laboratory's analysis of the next proficiency testing study results in three failed proficiency testing

studies, the laboratory shall be revoked for each affected accredited field of testing as defined in NELAC Chapter 2.

c) Reasons for total revocation include a laboratory's:

1) Failure to respond with a corrective action report within the required 21 working days.

2) Failure to participate in the proficiency testing program as required by the NELAC standards, Chapter 2.

3) Submittal of proficiency test sample results generated by another laboratory as its own.

4) Misrepresentation of any ~~material~~ fact pertinent to receiving initial approval.

5) Denial of entry during normal business hours for an on-site assessment as required by the NELAC standards, Chapter 3.

6) Conviction of charges ~~for~~ relating to the falsification of any report ~~of or~~ relating to a laboratory analysis.

7) Failure to remit the accreditation fees, if applicable,within the time limit as established by the accrediting authority shall ~~may~~ be grounds for immediate revocation.

d) After correcting the reason/cause for total revocation, the laboratory may reapply for accreditation no sooner than 6 months from the official date of revocation.

e) No laboratory's accreditation shall ~~will~~ be revoked without the right to due process. ~~as set forth in Section 4.7 of this Chapter.~~

4.4.4 Voluntary Withdrawal

If an environmental laboratory wishes to withdraw from NELAP, in total or in part, it must notify the primary accrediting authority no later than 21 working ~~30~~ days before the end of the accreditation year.

4.5 INTERIM ACCREDITATION

4.5.1 Interim Accreditation

If a laboratory completes all of the requirements for accreditation except that of an on-site assessment because the accrediting authority is unable to schedule the assessment in a timely manner, the accrediting authority may issue an interim accreditation. Interim accreditation shall ~~will~~ allow a laboratory to perform analyses and report results with the same status as an ~~fully~~ accredited laboratory until the on-site assessment requirements have been completed. Interim accreditation status shall ~~may~~ not exceed twelve months. The interim accreditation status is a matter of public record and shall ~~will~~ be entered into the National Database.

4.5.2 Revocation of Interim Accreditation

Revocation of interim accreditation may be initiated for due cause as described in 4.4.0 by order of the primary accrediting authority.

4.6 AWARDING OF ACCREDITATION

When a participating laboratory has met the requirements specified for receiving accreditation, the laboratory shall ~~will~~ receive a ~~single~~ certificate awarded on behalf of the ~~state~~ accrediting authority. The certificate shall ~~will~~ provide the following information: the name of the laboratory, address of the laboratory, the specifications of the accreditation action (for example, the laboratory may be accredited for analysis of water or for use of a specific analytical methodology, etc.). Addenda or attachments to the certificate are allowed and shall ~~will~~ be considered to be official documents. Information on the addenda or attachments may include scope, methods, analytes...etc. The laboratory must have a certificate for each state in which it is accredited. Even though a parent laboratory is accredited, the subfacilities (laboratories operating under the same parent organization, analytical procedures, and quality assurance system) are inspected or processed separately and shall ~~will~~ be issued their own Certificate of Accreditation. Any subfacilities or remote laboratory sites are considered separate sites and subject to separate ~~A~~announced and ~~U~~unannounced ~~A~~assessments, again provided that the analysis or any portion of the analysis take place at that site.

4.6.1 The Certificate of Accreditation

The certificate shall ~~will~~ be signed by a member of the accrediting authority and shall ~~will~~ be considered an official document. It will be transmitted as a sealed and dated (effective date and expiration date)document containing the NELAC Insignia. The certificate shall ~~will~~ include specific fields of testing, ~~categories~~, analytes, and methods that the laboratory or subfacility ~~site~~ is accredited for.

~~To address the concern that an individual state may revoke a laboratory's accreditation for work in that state,~~ tThe certificate shall ~~will~~ explain that continued accredited status depends on successful ongoing participation in the program. The certificate shall ~~will~~ urge a customer to verify the laboratory's current accreditation standing within a particular state. The certificate must be returned to the accrediting authority upon loss of accreditation. However, this does not require the return of a certificate which has simply expired (reached the expiration date).

4.6.2 Use of NELAC Accreditation by Accredited Laboratories

An accredited laboratory shall not misrepresent its NELAP accredited fields of testing, methods, analytes, or its NELAP accreditation status on any document. This includes laboratory reports, catalogs, advertising, business solicitations, proposals, quotations or other materials. (pursuant to NELAC Chapter 6.8)

4.6.~~2~~3 Changes in Fields of Testing

If an accredited laboratory changes its scope of accreditation, a new certificate shall ~~will~~ be issued which details the laboratory’s ~~spectrum of~~ accreditation(s).

4.7 ENFORCEMENT

Since NELAP is a standard setting body, it can not enforce civil or criminal penalties but rather all enforcement actions are taken independently by the accrediting authorities. ~~USEPA or state agencies and communicated to all other NELAC participating agencies. Any civil/criminal actions are taken by participating agencies and/or accrediting authorities.~~

The ~~development of an~~ enforcement component of the accrediting authorities ~~National Environmental Laboratory Accreditation Program (NELAC)~~ should be based on explicit

values, or principles, with which all participants concur. The proposed basic principles are:

a) The program should be equitable to all participants;

b) The rules should be well publicized;

c) The program needs of the participating agencies must be upheld; and

d) The due process rights of participating laboratories must be protected.